



AMERICAN FEED INDUSTRY ASSOCIATION

June 25, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, Maryland 20857

RE: Docket No. 99P-0033 (Humane Farming Association Petition)

Dear Food and Drug Administration:

This comment is submitted by the American Feed Industry Association (AFIA) in opposition to the actions sought by the Humane Farming Association (HFA), regarding combatting the spread of transmissible spongiform encephalopathies (TSEs) in the United States.

AFIA is the national trade association of the commercial feed and pet food manufacturing and related industries. AFIA represents over 700 feed and pet food manufacturers and distributors, ingredient suppliers, feed manufacturing equipment manufacturers, animal health product distributors, and animal drug manufacturers. AFIA members manufacture over 75% of the primary, commercial feed distributed in the U.S.

AFIA believes it is vital to American agriculture and American consumers to have the maximum protection reasonably possible against the possible introduction and spread of TSEs. AFIA is an active participant, both individually and as a member of the Animal Industry Coalition, in the rulemaking that led to FDA's current mammalian protein feeding restrictions. AFIA is active in educating its members, as well as a cosponsor of FDA's 1998 national satellite video conference to educate persons in affected industries about the new feeding restrictions.

In the face of widely conflicting views and divergent scientific opinions, AFIA applauds the agency for developing a workable, science-based approach. FDA's final rule, like other agency decisions, was based on FDA's interpretation of the available scientific evidence. In contrast, many of the key points in the HFA petition are supported only by citations to the popular and literary press, rather than citations to scientific and medical. HFA's citations, and the arguments in the petition upon which they depend, must be

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disregarded. Some other aspects of the HFA petition are supported by citations to recognized medical and scientific journals; however, they are based on old science long predating FDA's rulemaking. These arguments must also be disregarded.

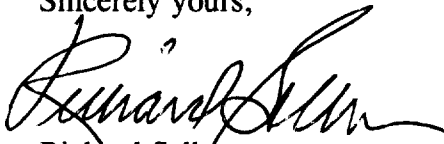
HFA asks FDA to terminate a number of exemptions in the final rule, including the exemptions for blood and blood products, gelatin and gelatin byproducts, and single species porcine protein. In its rulemaking preambles, FDA explained in detail its scientific and policy rationale for exempting these products and species.

FDA's final rule was published in the *Federal Register* over two years ago, and has been in effect for almost two years. Despite the widespread applicability of these requirements, AFIA is unaware of any generally accepted scientific studies -- or any other credible evidence, for that matter -- indicating that any of these exempted products presents a greater risk than FDA contemplated.

While AFIA is saddened by the suffering and death caused by Creutzfeldt-Jakob Disease (CJD) referenced in the petition, nothing in the petition provides any basis for concluding that these cases are from transmissible forms of CJD, or that there is any link with animal feeding practices in this country. AFIA urges FDA to contact the federal Centers for Disease Control and Prevention regarding any epidemiological work that may have been done in connection with the cases cited in the petition.

In sum, the HFA petition must be rejected because it is not based on generally accepted scientific principles. AFIA appreciates this opportunity to comment.

Sincerely yours,

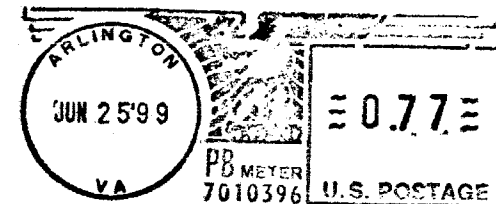
A handwritten signature in black ink, appearing to read "Richard Sellers", written in a cursive style.

Richard Sellers

Director of Feed Control and Nutrition



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